

K102539

P.1/2

8. 510(k) Summary

1. Applicant

Shoulder Options, Inc.
3284 Scenic Drive
Boise, ID 83703

FEB 24 2011

Contact Person: Mike Alexander, CEO
Tel: (208)761-1176
Fax: (888)760-2993
Email: alexander@shoulderoptions.com

Application Correspondent:

Kapstone Medical, LLC
100 E. South Main St.
P.O. Box 1458
Waxhaw, NC 28173

Contact Person: John Kapitan, President, Kapstone Medical LLC
Tel: (704) 843-7852
Fax: (704) 831-5316
E-mail: jkapitan@kapstonemedical.com

Date Prepared: September 1, 2010

2. Device Name

Common/Usual Name: Fastener, Fixation, Nondegradable, Soft Tissue
Classification Name: Smooth or threaded bone fixation fastener
Regulation Number: 888.3040
Product Code: MBI
Classification: II
Panel: Orthopedic

3. Predicate Devices

The Cuff Repair Plate™ (CRP) is substantially equivalent to the following device:

510(k) Number	Device	Manufacturer
K994364	Synthes Button Plate	Synthes

4. Description of the Device

The Cuff Repair Plate (CRP) is a fixable suture anchor plate that is designed to improve anchorage-to-bone strength during rotator cuff tendon-to-bone repair. When assembled, the device consists of a contoured, D-shaped buttress bone plate that is coupled to two anchor bolts. The plate is available in both right and left configurations. Anchor bolts are available in various lengths. Both the plate and the anchor bolts are manufactured from Ti-6Al-4V (ASTM F136). The components are provided non-sterile for single-use. The CRP is for use with #2 or #5 polyethylene-based high-strength non-absorbable braided suture.

5. Indications for Use

The Cuff Repair Plate is intended for augmentation of transosseous rotator cuff repair, especially in massive tears and reruptures in proximity to osteopenic bone.

6. Summary of Performance Data

Testing of the CRP device to demonstrate substantial equivalence included construct pull-out testing, CRP static three-point bending, and testing to evaluate the anchor bolt's torsional strength, insertion driving torque, and axial pull-out.

7. Safety & Effectiveness

The Cuff Repair Plate™ (CRP) is substantially equivalent to the Synthes Button Plate (SBP) (K994364). Both devices have the same "Indications for Use," are available by prescription only, and are provided non-sterile for single-use only. The CRP differs from the SBP in that the CRP uses anchor bolts for fixation, has a different plate design, and is made from titanium alloy. These differences do not negatively impact the overall safety and effectiveness of the device. Therefore, it can be concluded that the CRP is both a safe and effective device and is substantially equivalent to the SBP.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Shoulder Options, Inc.
% Kapstone Medical, LLC
Mr. John Kapitan
100 E. South Main Street
P.O. Box 1458
Waxhaw, North Carolina 28173

FEB 24 2011

Re: K102539

Trade/Device Name: Cuff Repair Plate™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 22, 2010
Received: December 27, 2010

Dear Mr. Kapitan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

Page 2 - Mr. John Kapitan

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102539

r 1/1

7. Indications for Use Statement

510(k) Number (if known): _____

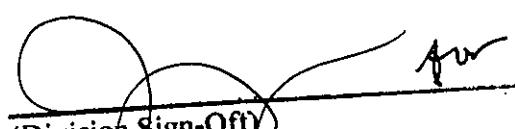
Device Name: Cuff Repair Plate™

Indications for Use:

The Cuff Repair Plate™ is intended for augmentation of transosseous rotator cuff repair, especially in massive tears and reruptures in proximity to osteopenic bone.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102539